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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO |
|--|----------------|----------------------|---------------------|-----------------|
| 10/058,540 | 01/28/2002 | Ronald D. Russo | R-17 | 3722 |
| 7: | 590 10/15/2004 | | EXAMINER | |
| Robert J. Doherty | | | MENDOZA, MICHAEL G | |
| 10-11 George St. Barrington, RI 02806 | | | ART UNIT | PAPER NUMBER |
| , | | | 3731 | |

DATE MAILED: 10/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| • | | | | | |
|---|---|--|--|--|--|
| | Application No. | Applicant(s) | | | |
| | 10/058,540 | RUSSO, RONALD D. | | | |
| Office Action Summary | Examiner | Art Unit | | | |
| | Michael G. Mendoza | 3731 | | | |
| The MAILING DATE of this communication a Period for Reply | ppears on the cover sheet with | h the correspondence address | | | |
| A SHORTENED STATUTORY PERIOD FOR REP THE MAILING DATE OF THIS COMMUNICATION - Extensions of time may be available under the provisions of 37 CFR after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a re - If NO period for reply is specified above, the maximum statutory perion - Failure to reply within the set or extended period for reply will, by state Any reply received by the Office later than three months after the mail earned patent term adjustment. See 37 CFR 1.704(b). | I. 1.136(a). In no event, however, may a reply within the statutory minimum of thirty od will apply and will expire SIX (6) MONT ute, cause the application to become ABA | ply be timely filed (30) days will be considered timely. HS from the mailing date of this communication. INDONED (35 U.S.C. § 133). | | | |
| Status | | | | | |
| 1) Responsive to communication(s) filed on 27 | July 2004. | | | | |
| 2a)⊠ This action is FINAL . 2b)☐ Th | <u>_</u> | | | | |
| · | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | |
| Disposition of Claims | | | | | |
| 4a) Of the above claim(s) is/are withdom 5) Claim(s) 47-66 is/are allowed. 6) Claim(s) 1, 2, and 4-11 is/are rejected. 7) Claim(s) is/are objected to. | Claim(s) 1, 2, and 4-11 is/are rejected. | | | | |
| Application Papers | | | | | |
| 9) The specification is objected to by the Examination The drawing(s) filed on is/are: a) and an applicant may not request that any objection to the Replacement drawing sheet(s) including the correction. The oath or declaration is objected to by the | ccepted or b) objected to be ne drawing(s) be held in abeyand ection is required if the drawing(s | ce. See 37 CFR 1.85(a). s) is objected to. See 37 CFR 1.121(d). | | | |
| Priority under 35 U.S.C. § 119 | | | | | |
| 12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority docume 2. Certified copies of the priority docume 3. Copies of the certified copies of the prapplication from the International Bure * See the attached detailed Office action for a li | ents have been received. ents have been received in Apriority documents have been reau (PCT Rule 17.2(a)). | oplication No received in this National Stage | | | |
| Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/0 Paper No(s)/Mail Date | Paper No(s) | ummary (PTO-413) /Mail Date formal Patent Application (PTO-152) | | | |

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DETAILED ACTION

Response to Arguments

- 1. Applicant's arguments filed 27 July 2004 have been fully considered but they are not persuasive.
- 2. In response to applicant's argument that the instant application is a closed tracheal suction system and that the Page reference is an open tracheal suction system, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).
- 3. In response to applicant's argument that the Page reference does not hermetically seal off fluids and air flow communication between the suction tube and the source of suction; Page discloses that the valve is a seal (col. 6, lines 38-42). The applicant argues that Page does not teach a seal because the width and thickness of the valve plate are slightly less than the width and thickness of the valve slot. The purpose of the differences is to allow the plate to fit into the slot. It the plate was the same size as the slot, the plate would not be able to fit into the slot. Furthermore, Page states the fitment of the plate to the slot forms a seal (col. 11, lines 1-7).

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4. The Applicant points out; page 15, 3rd full paragraph, that the actuator 282 may reciprocate up and down loosely through aperture 316. Aperture 316 is part of a retainer cap 310 for holding disc diaphragm bottom 278 and flange 280 in sealing engagement with flange 246 and upper edge 280. The ability for the actuator to reciprocate up and down loosely is to allow for easy operation of the actuator through aperture 316. There is no path for air to follow or air to escape through 316. It does not affect the seal formed by the valve plate and slot (see also col. 6, lines 38-42).

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 6. Claims 1, 3-5, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Page et al. 5215522.
- 7. Page et al. teaches a suction system having a suction tube, a source of suction and a suction control valve, the suction control valve comprising: a housing having an upper surface and a first central linear passageway extending through the housing and in fluid flow communication at one end thereof with a suction tube and with a suction source at the other end thereof, the housing having a second passageway opening at the upper surface and transversing the first central linear passageway, a manually depressible and releasable plunger operable with the second passageway wherein the plunger includes a closed piston portion and an open unobstructed, straight through,

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high flow cross lumen portion, the piston including outer surfaces adapted for sealing engagement with the second passageway, the piston being normally positioned with the second passageway to a non-suction applied position where the piston portion is posited across the first passageway so as to form a leak proof and airtight slideable seal to hermetically seal off fluid and air flow communication between the suction tube and the source of suction; wherein the plunger includes outer surfaces adapted for sealing engagement with the second passageway; a suction catheter and an actuator portion as part of the plunger, the first central linear passageway in fluid flow communication at one end with a suction catheter and at its other end with a suction source; and wherein the system is a closed tracheal suction system.

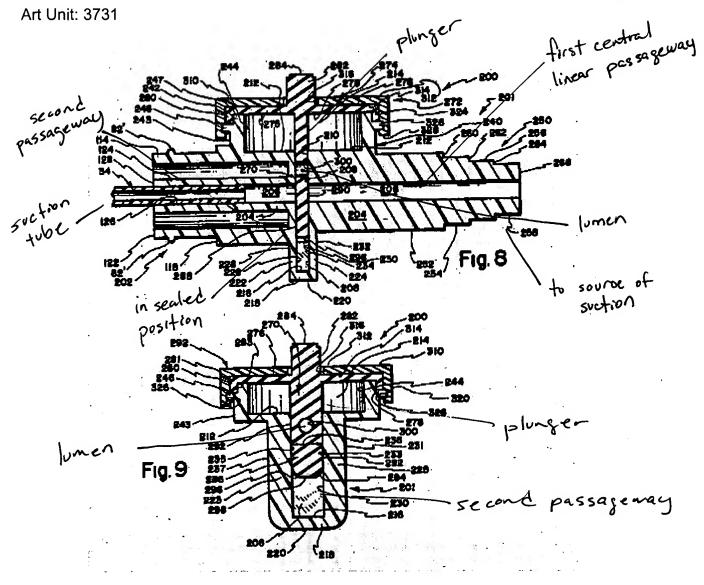
Claim Rejections - 35 USC § 103

- 8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 9. Claims 2, 6, and 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Page et al. in view of Palmer 4569344.
- 10. Page et al. teaches the suction control valve of claim 4. It should be noted that Page et al. fails to teach a means for preventing inadvertent depression of the plunger.
- 11. Palmer teaches a suction control valve with a common means for preventing inadvertent depression of a plunger. Therefore it would have been obvious to one

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having ordinary skill in the art at the time the invention was made to include the mean for preventing inadvertent depression of a plunger for preventing suction if not needed (col. 2, lines 2-3).

12. Page/Palmer teaches a respiratory suction catheter system as above for suctioning secretion from a patient further comprising: a frontal manifold 32 configured for delivery of ventilator air to a patient, a rearward suction control valve 40; a means for cleaning the catheter (col. 9, lines 26-37); wherein the frontal manifold is fixedly connected to a suction catheter assembly (col. 4, lines 20-25); wherein the suction catheter assembly is disconnectable with the frontal manifold (col. 4, lines 20-25).



Allowable Subject Matter

- 13. Claims 47-66 are allowable over the prior art of record.
- 14. The following is a statement of reasons for the indication of allowable subject matter: the prior art of record fails to teach or render obvious the overall claimed invention of a suction catheter system for suctioning secretions from a patient comprising: a catheter isolator seal disposed at a rearward end of a connector inner air passage, a catheter cleaning chamber including a catheter clean flush port located in

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front of the catheter isolator seal, the isolator seal normally biased to a closed position; the catheter isolator seal operable to an open position solely by direct contact and manual advancement of a distal tip of the catheter with the isolator seal.

Conclusion

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Mendoza whose telephone number is (703) 305-3285. The examiner can normally be reached on Mon.-Fri. 8:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Glenn Dawson can be reached on (703) 308-4304. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

WM.

MM October 12, 2004 GLENN K. DAWSON PRIMARY EXAMINER